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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/446,328	04/17/00	SPECK U	SCH1653

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EXAMINER	
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ART UNIT	**PAPER NUMBER**
1619	6

DATE MAILED: 09/27/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)	
	09/446,328	SPECK ET AL.	
	Examiner	Art Unit	
	Gary E Hollinden, Ph.D.	1619	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

1)☒ Responsive to communication(s) filed on *18 July 2000* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a)☐ All b)☐ Some * c)☐ None of the CERTIFIED copies of the priority documents have been:

1.☐ received.

2.☐ received in Application No. (Series Code / Serial Number) _____ .

3.☒ received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)
16) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *5* .
18) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other:

Claims 1-17 have been presented for examination and will be reviewed on their merits.

The Information Disclosure Statement received on July 18, 2000 has been entered and was fully considered in this Office Action.

This application has been filed with informal drawings which are acceptable for examination purposes only. Formal drawings will be required when the application is allowed.

Claims 7 and 8 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In particular, claim 7 is rendered confusing by the phrase "more highly-molecular" since it is both improper english and is a relative term which does not communicate the metes and bounds of the claim. Claim 8 is rendered confusing by the term "molecule associates" because it is improper syntax.

Claims 1-17 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-17 provide for the use of intravenous contrast media, but, since the claim does not set forth any steps involved in the method/process, it is unclear wthat method/process Applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 1-17 are rejected under 35 U.S.C. § 101 because the claimed invention of a use, without setting forth any steps involved in the process, results in an improper definition of a proccess, i.e., results in a claim which is not a proper process claim under 35 U.S.C. § 101. See, for example, *ex parte Dunki*[1] and *Clinical Products v. Brenner*[2].

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[1]153 USPQ 678, (Bd. Pat. App. & Inter. 1966)

[2]149 USPQ 475, (DDC 1966).

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

> "A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States."

Claims 1-17 are rejected under 35 U.S.C. § 102(b) as being anticipated by Teifke et al. (Fortschr. Rontgenstr. 161(6):495-500, 1994), Chang et al. (Radiology 132:647-652, 1979), Gisvold et al. (Mayo Clin Proc. 52:181-185, 1977), Kaiser et al. (Geburtsh u. Frauenheilk. 53:1-14, 1993), Pierce et al. (Radiology 181:757-763, 1991), Kenney et al. (Eur. J. Radiology 24:109-119, 1997), Helbich et al. (Radiology 202:421-429, 1997), Ranney (5,260,050; PTO-892 dated 9/26/00), Brasch et al. (6,009,342; PTO-892 dated 9/26/00), and Hilger et al. (5,849,259; PTO-892 dated 9/26/00).

These claims appear to be directed towards a use of contrast media. In order to expedite prosecution, the instant use claims will be examined as directed to a method of performing mammography comprising administering a barium or iodine containing x-ray and subsequently performing an x-ray examination of the breasts or conversely administering a paramagnetic metal ion containing MRI contrast agent and performing a MR diagnosis of the breasts.

Teifke et al., Chang et al. , and Gisvold et al. each teach a method of using iodine or bromine containing intravenous contrast agent for computed tomography of the breast. Kaiser et al., Pierce et al., Kenney et al., Helbich et al., Ranney (col. 41; tables 2 and 3), Brasch et al. (example 2), and Hilger et al. (example 23b) each teach the use of intravenous administration of paramagnetic agents for MR imaging of the breasts. Therefore, those claims generically drawn to a method of using an iodine, bromine or paramagnetic ion containing contrast agent for diagnostic mammography are anticipated as would be claims drawn to the specific imaging agents used by the prior art.

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Claims 1-17 are rejected under 35 U.S.C. § 103 as being unpatentable over Teifke et al. (Fortschr. Rontgenstr. 161(6):495-500, 1994), Chang et al. (Radiology 132:647-652, 1979), Gisvold et al. (Mayo Clin Proc. 52:181-185, 1977), Nitecki et al. (5,756,066; PTO-892 dated 9/26/00), Kaiser et al. (Geburtsh u. Frauenheilk. 53:1-14, 1993), Pierce et al. (Radiology 181:757-763, 1991), Kenney et al. (Eur. J. Radiology 24:109-119, 1997), Helbich et al. (Radiology 202:421-429, 1997), Ranney (5,260,050; PTO-892 dated 9/26/00), Brasch et al. (6,009,342; PTO-892 dated 9/26/00), Hilger et al. (5,849,259; PTO-892 dated 9/26/00), Kirpoitin et al. (5,411,730; PTO-892 dated 9/26/00), and Platzek et al. (6,054,117; PTO-892 dated 9/26/00).

These claims appear to be directed towards a use of contrast media. In order to expedite prosecution, the instant use claims will be examined as directed to a method of performing mammography comprising administering a barium or iodine containing x-ray and subsequently performing an x-ray examination of the breasts or conversely administering a paramagnetic metal ion containing MRI contrast agent and performing a MR diagnosis of the breasts.

Teifke et al., Chang et al. , Gisvold et al., and Nitecki et al. (col. 2, lines 32-35) each teach a method of using iodine or bromine containing intravenous contrast agent for computed tomography of the breast. Kaiser et al., Pierce et al., Kenney et al., Helbich et al., Ranney (col. 41; tables 2 and 3), Brasch et al. (example 2), Hilger et al. (example 23b), Kirpoitin et al. (cols. 11 and 12), and Platzek et al. (col. 21, lines 36-45), each teach the use of intravenous administration of paramagnetic agents for MR imaging of the breasts.

While the cited prior art does not teach all of the possible iodine, bromine and paramagnetic compounds that could be used for mammography, it would have been obvious to those of ordinary skill in the art that essentially any known contrast agent could be used because the cited prior art clearly teaches that a wide variety of contrast media have been used to obtain improved images for various modalities of breast diagnosis. One of ordinary skill would have been motivated to substitute whichever known contrast agent produces good contrast with minimum side effects.

The claimed subject matter fails to patentably distinguish over the state of the art as represented by the cited references. Therefore, the claims are properly rejected under 35 U.S.C. § 103.

The prior art made of record and not specifically relied upon in any rejections cited above is either 1) considered cumulative to the prior art that was cited in a rejection or is 2) considered pertinent to applicant's disclosure and shows the state of the art in its field but is not determined by the Examiner to read upon the invention currently being prosecuted in this application.

In view of the objections /rejections to the pending claims set forth above, no claims may be allowed at this time.

The processing of this application can be expedited by providing the following information or changes in your next amendment:

- Proper cross-reference to related applications for which priority is claimed under 35 U.S.C. § 120 in the first paragraph of the specification - including current status (M.P.E.P. 201.11)
- Early filing of an Information Disclosure Statement that includes a PTO-1449 form wherein the document number, publication date, inventor, country of publication, and US patent classification is listed for each patent document and wherein the author, title, journal, volume, issue (if known), pages, and year of publication is listed for all journal references (M.P.E.P. 609). A timely prior art disclosure by the Applicant aids in a speedy prosecution and helps to insure that the patent granted is both valid and enforceable.
- A descriptive title (M.P.E.P. 606 and 606.01). Please note that 1-2 word titles are generally unacceptable.
- Ensuring that each of the drawings presented (if any) are described in the brief description of the drawings. Please note that if a drawing has more than one

figure in it (e.g. Figures 1A and 1B), each of the figures must be individually described.

- An abstract which is descriptive of the disclosed invention and contains the chemical structure of the active ingredient(s).
- Correction of any ambiguities in the specification which may lead to a printer inquiry, such as blank spaces which appear to be omissions.
- Correction of any typographical errors in the application.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to the Group 1600 fax machine at 703/308-4556. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30; November 15 1989.

Any inquiry concerning this Office Action or any earlier Office Actions in this application should be directed to Dr. Gary E. Hollinden whose telephone number is 703/308-4521. Dr. Hollinden's office hours are from 6:30 am to 3:00 pm on Monday through Friday.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is 703/308-1235.

Gary E. Hollinden, Ph.D.
Primary Examiner
Group 1600